

## **REMARKS**

Claims 1-20 are now pending in the application. By this Paper, Claim 1 has been amended and Claims 13-20 have been added. The basis for the foregoing amendments and new claims can be found throughout the specification, claims, and drawings originally filed. No new matter has been added. The preceding amendments and the following remarks are believed to be fully responsive to the outstanding Office Action and are believed to place the application in condition for allowance. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments contained herein.

### **REJECTIONS UNDER 35 U.S.C. §§ 102 AND 103**

Claims 1, 2, 4, 5, and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Matsuda et al. (U.S. Pat. No. 5,688,252).

Claim 3 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuda et al.

Claims 6-11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuda et al.

These rejections are respectfully traversed.

Applicants respectfully submit that Matsuda fails to teach or suggest a prefilled medical syringe including a thread system having a thread sleeve with an internal thread that cooperates with an outer thread on a plunger rod, whereby rotation of the plunger rod into meshed engagement with the internal thread of the thread sleeve causes the plunger rod to be displaced and move toward a cannula of the syringe.

Furthermore, Applicants respectfully submit that Matsuda also fails to disclose a prefilled medical syringe including a plunger rod having an outer thread and a thread sleeve having an inner thread, whereby engagement of the inner thread with the outer thread ruptures a membrane.

Matsuda discloses a two-component type prefilled syringe (K1) including a tubular body (1), a gasket (2), and a plunger rod (3). See Matsuda at Col. 8, Ins. 43-66, and Figure 6. The gasket (2) is received within the tubular body (1) and includes a female screw (21). See Matsuda at Col. 9, Ins. 23-30, and Figures 6 and 7. The plunger rod (3) includes a male screw (31) disposed at a distal end thereof for selective engagement with the female screw (21) of the gasket (2). See Matsuda at Col. 9, Ins. 32-61, and Figures 6, 8, and 9.

In operation, the male screw (31) is inserted into the female screw (21) of the gasket (2) such that the plunger rod (3) is fixed for movement with the gasket (2). See Matsuda at Col. 10, Ins. 22-59, and Figure 9. Once the plunger rod (3) is fixed to the gasket (2) via engagement between the male screw (31) and the female screw (21), a force may be applied to the plunger rod (3) to move the plunger rod (3) and gasket (2) along a longitudinal axis of and relative to the tubular body (1) of the syringe (K1). See Matsuda at Col. 10, Ins. 60-65.

As described above, insertion of the male screw (31) of the plunger rod (3) into the female screw (21) of the gasket (2) does not advance either the plunger rod (3) or the gasket (2) relative to the tubular body (1). Rather, rotation of the plunger rod (3) relative to the gasket (2) only moves the plunger rod (3) along a longitudinal axis of the

tubular body (1) and such movement along the longitudinal axis is only permitted until the male screw (31) is connected to the female screw (21) of the gasket (2).

Once the male screw (31) is attached to the female screw (21), movement of the plunger rod (3) and gasket (2) relative to the tubular body (1) is accomplished *only* by applying an external force to the plunger rod (3) along the longitudinal axis of the tubular body (1). See Matsuda at Col. 10, Ins. 60-65. In other words, secondary operation is required to advance the plunger rod (3) relative to the tubular body (1)—namely a force applied to the plunger rod (3) to advance both the gasket (2) and the plunger rod (3). Applicants note that the Examiner appears to agree with the foregoing characterization of Matsuda, as the Examiner indicates at Page 5 of the Office Action mailed October 16, 2008, that once the threaded sections of Matsuda are engaged and “*the plunger is pushed*,” pressure increases inside an inner space of the device of Matsuda. *Emphasis added.*

Based on the foregoing, Applicants respectfully submit that independent Claims 1 and 6, as well as Claims 2-5 and 7-12, respectively dependent therefrom, are in condition for allowance. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

#### **NEW CLAIMS**

New Claims 13-20 are added for consideration. Because the cited art of record fails to teach or suggest a prefilled medical syringe including a syringe plunger disposed in an inner space of a syringe barrel and coupled to a first end of a plunger rod, whereby the plunger rod has an outer thread that is formed between the first end and a

second end and a non-threaded portion is disposed between the outer thread and the first end or a thread system including a thread sleeve having an inner thread that cooperates with the outer thread on the plunger rod to move the plunger rod relative to the syringe barrel, Applicants respectfully submit that independent Claim 13, as well as Claims 14-20, dependent therefrom are in condition for allowance.

### CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Dated: 1/16/09

Respectfully submitted,

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